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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,384	01/16/2007	Alastair David Griffiths Lawson	07-1008-WO-US	1913

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
08/31/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,384	LAWSON ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-14 and 16-25* is/are pending in the application.

4a) Of the above claim(s) *13,14,20 and 23-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12, 16-19, 21, 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/21/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 06/21/2010, has been entered.

Claims 12 and 16-19 have been amended.

Claim 15 has been canceled.
Claims 1-11 have been canceled previously.

Claims 12-25 are pending.

Claims 12, 16-19 and 21-22 are under consideration as they read on treating inflammatory bowel disease (e.g., ulcerative colitis and Crohn's disease) with anti-CSF-1 antibody (i.e., anti-M-CSF antibody) as they read on the elected invention and species.

Claims 13-14, 20 and 23-25 have been withdrawn from further consideration by the examiner as being drawn to a nonelected inventions and/or species.

2. This Office Action will be in response to applicant's amendment, filed 06/21/2010.

The rejections of record can be found in the previous Office Action, mailed 01/21/2010.

3. Upon reconsideration of applicant's provision of a supplemental Application Data Sheet that provided the missing information noted in the previous Office Action, mailed 01/21/2010
and the petition to correct the inventorship and supporting papers, filed 10/13/2009, and supplemented with the Application Data Sheet, filed 06/21/2010;
it has been found that this application, as filed, without any deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 C.F.R. § 1.48.

The inventorship of this application has been changed by adding Diane Marshall as an inventor. The instant inventors are Lawson, Burnham and Marshall.

4. Upon reconsideration of applicant's submission of the supplemental Application Data Sheet, filed 06/21/2010,
in conjunction with the Declaration, filed under 37 CFR 1.131, filed 10/13/2009 ,
the previous rejection under 35 U.S.C. § 102(e) as being anticipated by over Bedian et al. (US 2005/0059113) has been withdrawn.

5. Claims 12, 16-17, 19 and 21-22 are rejected under 35 U.S.C. § 102(e) as being anticipated by Devalaraja et al. (U.S. Patent No. 7,108,852) and as further evidenced by page 1, paragraph 3 of the instant specification with respect to the well known meaning of IBD by the ordinary artisan at the time the invention was made essentially for the reasons of record.

Applicant's arguments in conjunction with Impax Laboratories, Inc. v. Aventis Pharmaceuticals, 88 USPQ2d 1381 (Fed. Cir. 2008), filed 06/21/2010, have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant argues that Devalaraja et al. is directed to the general proposition that agents that inhibit the production or activity of CSFs can be used in treatment, but does not provide any examples of animal testing or models of any of the diseases to be treatable by the claimed methods. In turn, applicant asserts that Devalaraja et al. engages in mere speculation as to the effect of such inhibitors in the treatment of particular diseases (e.g., IBD) and has failed to demonstrate that M-CSF actually has a role in IBD. Applicant in conjunction with Impax asserts that Devalarja et al. was not enabling in that there is no guidance in the reference suggesting that inhibitors of M-CSF, as opposed to other cytokines or chemokines, would have any particular therapeutic value in the treatment of IBD, as opposed to any of the other autoimmune diseases / disorders mentioned and gives no working examples relating to actual models of any disease, including IBD.

As noted previously, the preferred use of inhibitors of CSF, including antibody directed to CSF (e.g., column 4, paragraphs 1-5) described by the prior art teaching is the treatment of IBD (e.g., see column 7, paragraph 1).

When the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. See Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) and MPEP 2131.02.

The teaching of record has properly shifted burden to applicant. (USSN 10403340)

The assertions of counsel cannot take the place of evidence in the record.

The unsupported assertion does not establish a fact.

A reference contains an enabling disclosure if the public was in possession of the claimed invention before the date of invention. Such possession is effected if one of the ordinary skill in the art would have combined the publication's description of the invention with his/her own knowledge to make the claimed invention. See In re Donohue, 226 USPQ 619 (Fed. Cir. 1985) and MPEP 2121.01.

The following is reiterated for applicant's convenience.

Devalaraja et al. teach treating various inflammatory conditions, including inflammatory bowel disease (e.g., see column 7, paragraph 1) with inhibitors of CSF, including antibody directed to CSF (e.g., column 4, paragraphs 1-5) and Detailed Description of the Invention (e.g., see column 10, paragraph 1; column 11, paragraph 6-9; column 13, paragraph 6 - column 14, paragraph 1) and Claims.

Devalaraja et al. notes that M-CSF was also known as colony stimulating factor-1 in the Background of the Invention (also, see in particular column 1, paragraph 3 of the Background) and the Summary of the Invention (see column 4 in particular).

As page 1, paragraph 3 of the instant specification acknowledges,
The ordinary artisan accepted the well known meaning of IBD as follows.
The term "inflammatory bowel disease" (IBD) refers to serious, chronic disorders of the intestinal tract characterized by chronic inflammation at various sites in the gastrointestinal tract, and specifically includes ulcerative colitis OAC) and Crohn's disease (CD).

Applicant's arguments have not been found persuasive.

6. Claims 12, 16-17, 19 and 21-22 are rejected under 35 U.S.C. § 102(e) as being anticipated by Hamilton et al. (U.S. Patent No. 7,455,836) and as further evidenced by page 1, paragraph 3 of the instant specification with respect to the well known meaning of IBD by the ordinary artisan at the time the invention was made essentially for the reasons of record.

Applicant's arguments, filed 06/21/2010, have been fully considered but have not been found convincing essentially for the reasons of record.

Like the Devalaraja et al. reference above, applicant argues that Hamilton et al. generally suggests the use of inhibitors of CSFs in the amelioration of inflammation in a subject.
Unlike Devalaraja et al., Hamilton et al. does describe animal studies which were models of asthma, COPD and collagen-induced arthritis.

As above, applicant asserts that Devalarja et al. was not enabling in that there is no guidance in the reference suggesting that inhibitors of M-CSF, as opposed to GM-CSF or u-PA, would have any particular therapeutic value in the treatment of IBD, as opposed to any of the other autoimmune diseases / disorders mentioned and gives no working examples relating to IBD.

As noted previously, Hamilton et al. teach methods of treating inflammatory conditions, such as inflammatory bowel disease and Crohn's disease (e.g., see Background of the Invention; column 5, paragraph 6; Claim 13) with antagonists of colony stimulating factor-receptor interactions, including colony stimulating factors such as M-CSF (e.g., see Summary of the Invention, Detailed Description of the Preferred Embodiments), including antibodies (e.g., see column 8, paragraphs 2 and 9; column 10, paragraph 2; column 12, paragraph 4; and Example 2).

When the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. See Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) and MPEP 2131.02.

The teaching of record has properly shifted burden to applicant. (USSN 10403340)

The assertions of counsel cannot take the place of evidence in the record.

The unsupported assertion does not establish a fact.

A reference contains an enabling disclosure if the public was in possession of the claimed invention before the date of invention. Such possession is effected if one of the ordinary skill in the art would have combined the publication's description of the invention with his/her own knowledge to make the claimed invention. See In re Donohue, 226 USPQ 619 (Fed. Cir. 1985) and MPEP 2121.01.

Applicant's arguments have not been found persuasive.

7. Claims 12, 16-19 and 21-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Devalaraja et al. (U.S. Patent No. 7,108,852) AND/OR Hamilton et al. (US 7,455,836) in view of Buschmann et al. (U.S. Patent No. 7,507,705), Renner et al. (US 2004/0053365) and as further evidenced by page 1, paragraph 3 of the instant specification with respect to the well known meaning of IBD by the ordinary artisan at the time the invention was made.

Applicant's arguments, filed 06/21/2010, have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant's arguments and the examiner's rebuttal concerning the teachings of Devalaraja et al. and/or Hamilton et al. have been addressed above.

Concerning the asserted deficiencies of Buschmann et al. and Renner et al. and the asserted complexity of IBD based upon the teachings of Sandorn et al. (Gastroenterology, 122: 1592-1608, 2002), Panes (Acta Physiol. Scand. 173: 159-165, 2001) and Baumgart et al. (Current Pharmaceutical Design 10: 4127-4147, 2004),

the examiner recognizes that obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine 5 USPQ2d 1596 (Fed. Cir 1988) and In re Jones 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case the teachings of prior art, including the primary references of Devalaraja et al. and Hamilton et al., pertaining to the use of CSF inhibitors, including M-CSF / CSF-1 inhibitors, in the treatment of IBD, to ameliorate the effects of inflammation in a subject by antagonizing CSF-mediated proliferation, activation, growth and/or survival of monocytes / macrophages and/or the production or activation of one or more inflammatory mediators from said monoctyes / macrophages would have led one of ordinary skill in the art at the time the invention was made to combine the references to solve a well known problem in the art.

The strongest rationale for combining reference is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent that some advantage or expected beneficial result would have been produced by their combination In re Sernaker 17 USPQ 1, 5-6 (Fed. Cir. 1983) see MPEP 2144

The following is reiterated for applicant's convenience.

Devalaraja et al. teach treating various inflammatory conditions, including inflammatory bowel disease (e.g., see column 7, paragraph 1) with inhibitors of CSF, including antibody directed to CSF (e.g., column 4, paragraphs 1-5) and Detailed Description of the Invention (e.g., see column 10, paragraph 1; column 11, paragraph 6-9; column 13, paragraph 6 - column 14, paragraph 1) and Claims.

Devalaraja et al. notes that M-CSF was also known as colony stimulating factor-1 in the Background of the Invention (also, see in particular column 1, paragraph 3 of the Background) and the Summary of the Invention (see column 4 in particular).

Hamilton et al. teach methods of treating inflammatory conditions, such as inflammatory bowel disease and Crohn's disease (e.g., see paragraphs [0004], [0036])with antagonists of colony stimulating factor-receptor interactions, including colony stimulating factors such as M-CSF (e.g., see Summary of the Invention, Detailed Description of the Preferred Embodiments)
including antibodies (e.g., see paragraphs [0040], [0062], [0073]).

Devalaraja et al. and Hamilton et al. differ from the claimed methods by not describing all of the well known functional equivalents of recombinant antibodies and antigen-binding fragments thereof at the time the invention was made.

Renner et al. teach methods of treating inflammatory conditions, with antagonists encompassing the well known functional equivalents of recombinant antibodies and antigen-binding fragments thereof, including chimeric and humanized antibodies as well as Fab and $F(ab')_2$ (e.g., see pages 1-3). at the time the invention was made, including the use of such antibodies in the context of the colony stimulating factor GM-CSF and inflammatory bowel disease (e.g., see paragraph [0040]) (see entire document, including Background and Prior Art, Summary of the Invention and Detailed Description of the Invention).

Similarly, Buschmann et teach the well known functional equivalents of recombinant antibodies and antigen-binding fragments thereof, including monoclonal, polyclonal and synthetic antibodies as well as Fab, Fv and scFv fragments (e.g., see column, 9,paragraph 6; column 10, paragraph 3 -column 11, paragraph 1), at the time the invention was made, including the use of such antibodies in the context of the colony stimulating factors, including M-CSF (e.g., see column 5, paragraph 31) (see entire document).

Consistent with the prior art teachings and as page 1, paragraph 3 of the instant specification acknowledges, the ordinary artisan accepted the well known meaning of IBD as follows.

The term "inflammatory bowel disease" (IBD) refers to serious, chronic disorders of
the intestinal tract characterized by chronic inflammation at various sites in the
gastrointestinal tract, and specifically includes ulcerative colitis OAC) and Crohn's disease (CD).

One of ordinary skill in the art at the time the invention was made would have been motivated to select various equivalent forms of CSF-1-/M-CSF-1-specific antibodiess having antagonistic properties in order to inhibit undesirable responses in inflammatory bowel disease at the time the invention was made;

given the teachings of Devalaraja et al. and Hamilton et al. to treat inflammatory bowel disease with antagonistic antibodies specific for CSF-1-/M-CSF-1 and the well known use of various antibody equivalents, including conjugated antibodies to one or more effector molecules, taught by Devalaraja et al. and Hamilton et al., as well as Renner et al. and Buschmann et al. in the context of therapeutic methods targeting colony stimulating factors as well as well known practiced by the ordinary artisan at the time the invention was made.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art goal was to treat inflammatory disease with CSF-1-specific antibodies, incorporating known methods of treating inflammatory conditions, including inflammatory bowel disease, with functional equivalents of antagonistic therapeutic antibodies including conjugated antibodies to one or more effector molecules would have been routine to the ordinary artisan at the time the invention was made and therefore obvious in designing therapeutic regimens associated with inflammatory bowel disease.

Applicant's arguments have not been found persuasive.

8. No claim is allowed.

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/
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